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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 14, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-15

Jerry L. Smith, Owner
Herbal Junction
P.O. Box 50041
Eugene, Oregon 97405

WARNING LETTER

Dear Mr. Smith:

The Food and Drug Administration (FDA) conducted an inspection of your tea manufacturing plant located at 180 East 30th Avenue, Eugene, Oregon, on September 10, 2003. Labels of your products were collected during the inspection. We have reviewed the label of your "Livertea and Justice Herbal Enzyme Elixer Tea." Our review shows that this product is represented for use as a conventional food and that the product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act and regulations through links in FDA's homepage at www.fda.gov.

Under the Act, any substance intentionally added to a conventional food must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction, or is generally recognized as safe (GRAS) among qualified experts for its intended use in foods. According to its label, your "Livertea and Justice Herbal Enzyme Elixer Tea" contains una de gato, peony, ho shou wu, muira pauma, chanca peidra, jatoba, and catuaba. We are not aware of any basis to conclude that these ingredients are the subject of a prior sanction or are GRAS for use in tea products. Nor are these substances used in accordance with a food additive regulation. Thus, the food containing these substances is adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)) and cannot be legally marketed in the United States.

The above violations are not an all-inclusive list of deficiencies in your facility or with your products. It is your responsibility to assure that all of your products and labels are in compliance with the Act and its implementing regulations. You should take prompt action to correct these deviations and prevent future recurrence. Failure to correct promptly may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Copies of revised labels should also be submitted. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state the time at which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913 or via e-mail at lelrand@fda.gov.

Sincerely,

Kristy D. Davis
for Charles M. Breen
District Director

cc: OSDA with disclosure statement

cc: Jerry L. Smith, Owner
Herbal Junction
180 East 30th Avenue
Eugene, Oregon 97405